

40 CFR Part 721

[OPPTS-50595; FRL3890-3]

RIN 2070-AC14

Toxic Substances; Significant New Use Rules; Proposed Amendment to Expedited Process for Issuing Significant New Use Rules; Proposed Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: Pursuant to section 5(a)(2) of the Toxic Substances Control Act (TSCA), EPA is proposing an amendment to the notification requirements for selected new chemicals (40 CFR 721.170(c)(1)) that would authorize EPA to impose any of the provisions in 40 CFR part 721 subpart B and other provisions not included in subpart B using expedited rulemaking procedures to promulgate "significant new use" rules (SNURs) for substances not subject to section 5(e) Orders. Currently, the notification requirements in § 721.170(c)(1) limit the type of activities which EPA can designate as a significant new use by expedited rulemaking without first issuing a section 5(e) Order. This proposed amendment would allow EPA to promulgate expedited SNURs for certain substances without issuing a section 5(e) Order for the substance, and thereby facilitate EPA's ability to efficiently and expeditiously regulate new chemical substances.

DATES: Comments must be received by April 9, 1993. If requested, EPA will conduct public hearings on the proposed rule amendments. Requests to make an oral presentation must be received by April 9, 1993.

ADDRESSES: All comments and requests to speak at the public hearing must be sent to: TSCA Document Control Office (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, DC 20460, (Phone: 202-260-1532).

Comments should include the docket control number. The docket control number for this amendment is OPPTS-50594. Since some comments may contain confidential business information (CBI), all comments must be sent in triplicate (with additional sanitized copies if CBI is involved). Comments on this proposed rule will be placed in the rulemaking record and will be available in the TSCA Public Docket Office, Rm. NE-G-004 at the above address between 8 a.m. and 12 noon and 1 p.m. and 4 p.m., Monday through Friday, excluding public holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543-B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: **Electronic Availability:** This document, along with three other related documents, OPPTS-50593, 50594, and 50596, is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the *Federal Register*. By modem dial (202) 512-1387 or call (202) 512-1530 for disks or paper copies. This document and the three related documents are available in Postscript, Wordperfect and ASCII.

SNURs require persons to notify EPA at least 90 days before commencing any manufacturing, importing, or processing activities designated by the SNUR as a significant new use. The supporting rationale and background for SNURs are more fully set out in the preamble to EPA's first SNURs issued under the Expedited Follow-Up Rule and published at 55 FR 17376 on April 24, 1990. Consult that preamble for further information on the objectives, rationale, and procedures for the rules and on the basis for significant new use designations.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). The enumerated factors pertain to the potential for increased manufacturing and processing volume, increased exposure, and anticipated methods of manufacture, processing, distribution and disposal. Once EPA determines that a use of a chemical substance is a

significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 721.10.

II. Applicability of General Provisions

General provisions for SNURs appear under subpart A of 40 CFR part 721. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of SNURs to uses occurring before the effective date of a SNUR. Rules on user fees appear at 40 CFR part 700. Persons subject to a SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(d)(1) and 5(b), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUR notice. If EPA does not take action, EPA is required under section 5(g) to explain in the *Federal Register* its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707.

III. Discussion of Proposed Amendment**A. Section 5 of TSCA**

Section 5(a)(1) of TSCA requires submission of written notice to EPA at least 90 days before commencement of commercial manufacture or import of a "new chemical substance" (which is a substance not listed on the TSCA Chemical Substance Inventory maintained pursuant to section 8(b)) and before manufacture or processing of any chemical substance for an activity which EPA determines, by rule, constitutes a "significant new use." Upon receipt of such a premanufacture notice (PMN) or significant new use notice (SNUN), if EPA determines that there is insufficient information to evaluate the human health and environmental effects of the substance, and that the substance may present an unreasonable risk of injury to health or the environment, or that the substance will be produced in substantial quantities and may be anticipated to

enter the environment in substantial quantities or there may be significant or substantial human exposure, then EPA may issue an Order under section 5(e) of TSCA to prohibit or limit activities associated with the substance.

After a company commences commercial manufacture or import of a PMN substance and submits a notice of commencement (NOC) of manufacture within 30 days as required by 40 CFR 720.102, EPA adds the substance to the TSCA section 8(b) Inventory. The substance is then no longer a "new chemical substance," as defined by section 3(a) of TSCA, the manufacture of which would require submission of a PMN. The requirements of a section 5(e) Order apply only to the company who submitted the notice, whereas a SNUR applies to all manufacturers and processors of the substance. Consequently, once a substance subject to a section 5(e) Order is listed on the TSCA section 8(b) Inventory, any other company may manufacture the substance without being required to notify EPA or comply with any other restrictions under section 5 of TSCA, unless EPA promulgates a SNUR pursuant to section 5(a)(2) of TSCA.

Therefore, EPA has adopted a policy that when the Agency has raised concerns for a substance and has regulated that substance under a section 5(e) Consent Order, EPA develops a SNUR concurrently with the Consent Order. The SNUR defines a significant new use so as to require reporting to EPA before a manufacturer (including importers) or processor undertakes activities inconsistent with provisions of the Consent Order. In this manner, the Agency will have an opportunity to review those activities before they occur because, under section 5(a)(1)(B) of TSCA, any company wishing to undertake the activities designated in the SNUR must submit a SNUN to EPA at least 90 days before doing so. Ordinary "notice and comment" rulemaking procedures to develop a SNUR require more time than development of a Consent Order. However, the Agency can promulgate SNURs using the expedited procedures for SNUR development at 40 CFR 721.160 or 721.170 (54 FR 31298, July 27, 1989). Using these expedited procedures, EPA can generally promulgate a SNUR within a time frame similar to that necessary to issue a section 5(e) Order.

B. Expansion of Activities Available for Designation as Significant New Uses in Expedited Non-5(e) SNURs

EPA's ability to promulgate SNURs efficiently and expeditiously has been

facilitated by EPA's New Chemical Follow-up Rule (also known as the "Generic SNUR"), published on July 27, 1989 (54 FR 31298; 40 CFR 721.50 - 721.185). The Generic SNUR established a generic list of standard significant new use designations and established that EPA would generally promulgate substance-specific SNURs using expedited rulemaking procedures instead of the standard "notice and comment" rulemaking. (See also the proposed rule at 52 FR 15594, April 29, 1987.) This rule was designed to, among other things, reduce the time between EPA's completion of the PMN review and promulgation of a SNUR.

EPA is exploring additional ways to speed Agency action on new chemical substances and conserve Agency resources in the TSCA section 5 program. Among these proposed activities is this amendment to expand the types of expedited SNURs for new chemical substances that EPA may promulgate directly without first issuing section 5(e) Orders (hereafter referred to as "non-5(e) SNURs") under 40 CFR 721.170. Whereas a section 5(e) Order applies only to the original PMN submitter who signs the Order, a SNUR applies to all manufacturers and processors of the chemical substance. The reporting requirements of a non-5(e) SNUR apply also to the original PMN submitter (because, without a section 5(e) Order, the PMN submitter is not exempted by 40 CFR 721.45(i)). Since only one Agency action is required instead of two, and fewer EPA resources are necessary to obtain similar regulatory results, a non-5(e) SNUR is more efficient than a combination of section 5(e) Order and "5(e)-SNUR" (under 40 CFR 721.160) to regulate new chemical substances.

A non-5(e) SNUR is typically appropriate for PMNs on chemical substances expected to be toxic but where the PMN indicates the submitter's intention to limit activities, implement control measures, or otherwise adequately mitigate human exposures and environmental releases. Activities described in such PMNs may not present an unreasonable risk of injury to human health or the environment so as to warrant the issuance of an Order under section 5(e) of TSCA, but deviations from the described activities may present an unreasonable risk warranting the imposition of regulatory controls via a section 5(e) Order. In those cases, a non-5(e) SNUR may be the least burdensome regulatory alternative for the Agency to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring

notification to, and review by, EPA for activities which have not been reviewed.

Based on experience gained from issuing over 200 SNURs under expedited follow-up procedures, EPA is proposing an amendment to 40 CFR 721.170(c)(1) that would authorize EPA to designate any of the provisions in 40 CFR part 721 subpart B using expedited rulemaking procedures to promulgate non-5(e) SNURs. EPA may currently use the more time-consuming notice and comment rulemaking to promulgate non-5(e) SNURs containing any of the significant new use designations in subpart B. However, section 721.170(c) currently limits the types of activities in subpart B which EPA can designate as a significant new use by expedited rulemaking without first issuing a section 5(e) Order. Significant new use designations available for expedited non-5(e) SNURs are currently limited to environmental release activities and certain industrial, commercial, or consumer activities. However, other important designations, such as protection in the workplace and hazard communication, currently may not be promulgated in non-5(e) SNURs via expedited rulemaking procedures. The absence of hazard communication provisions in current expedited non-5(e) SNURs may result in failure to inform persons handling substances of their potential risks and proper precautionary measures to protect against such risks. Furthermore, a large percentage of the new chemical substances that EPA regulates under section 5(e) are regulated to control workplace exposures. However, worker protection activities currently may not be designated as significant new uses in expedited non-5(e) SNURs. EPA should be able to select from all the possible designations in subpart B, in order to respond appropriately to the unique characteristics of the various new chemical substances which EPA reviews under section 5 of TSCA.

EPA already has the authority to designate hazard communication and worker protection provisions either by promulgating SNURs using notice and comment rulemaking procedures or by issuing a section 5(e) Order and promulgating an expedited "5(e)SNUR." However, this proposed amendment would enable EPA to designate hazard communication and worker protection provisions by promulgating SNURs using expedited rulemaking procedures and without issuing a section 5(e) Order.

In addition, this proposed amendment would authorize EPA to promulgate expedited non-5(e) SNURs with

provisions not currently listed in subpart B. Occasionally, EPA has promulgated expedited 5(e)-SNURs containing provisions not in subpart B when necessary to match the terms of the section 5(e) Order. An example of a non-subpart B provision that EPA sometimes includes in a chemical-specific expedited SNUR is a provision that allows a specified amount of removal credit for a specified wastewater treatment technology, since the standard provision at 40 CFR 721.91(a)(4) does not account for wastewater treatment removal.

Similarly, EPA may occasionally use expedited procedures to promulgate non-5(e) SNURs containing provisions not included in subpart B when the provision is necessary to match the information contained in the PMN. EPA uses expedited rulemaking to promulgate SNURs with a non-subpart B provision only when the provision represents a relatively minor deviation from the standard provisions in subpart B such that EPA does not anticipate a high likelihood of public interest in commenting on the provision. See 54 FR 31305, July 27, 1989. Nevertheless, as discussed below, the expedited procedures still provide interested parties an opportunity to comment on the SNUR.

C. Opportunity for Comment

The expedited rulemaking procedure for the Generic SNUR is based on EPA's experience which has demonstrated that very few comments on SNURs are submitted. (See, e.g., 52 FR 15596, April 29, 1987; 54 FR 31299, July 27, 1989.) However, the process EPA is proposing here is not intended to limit opportunity for public comment.

The current limitations in 40 CFR 721.170(c)(1) were contained in the original proposal of the Generic SNUR (52 FR 15596, April 29, 1987). As originally proposed, the Generic SNUR provided for immediately effective final SNURs. However, the final version of the Generic SNUR, as described below, "significantly changes the proposed approach to provide a greater opportunity for public comment" (54 FR 31299, July 27, 1989). EPA now believes that, given the expanded comment opportunity in the final Generic SNUR, the subpart B provisions available for expedited non-5(e) SNURs should be expanded.

Pursuant to the final Generic SNUR, EPA generally uses "direct final" rulemaking to promulgate follow-up SNURs on new chemical substances. Under direct final rulemaking procedures, EPA publishes the rule in the final rule section of the Federal

Register and the SNUR automatically becomes effective 60 days from publication unless, within 30 days after publication, EPA receives written notice that someone wishes to submit adverse or critical comments. If EPA receives such a notice, EPA will withdraw the final SNUR and propose the rule in the proposed rule section of the Federal Register, establishing a 30-day comment period. This procedure allows opportunity for public comment before a SNUR becomes effective, without unnecessarily delaying the rulemaking if no comments are likely to be submitted.

Furthermore, according to the current § 721.170(d)(2), at least 7 days before expiration of the PMN review period, EPA must notify the PMN submitter of the Agency's human health or environmental concerns and the activities under consideration for designation as a significant new use. This procedure provides ample notice to the person most likely to have an interest in providing comment (the PMN submitter). Thus, the expanded non-5(e) SNUR process proposed herein will still provide notice and opportunity for comment to all persons through the Federal Register and individual notice to the PMN submitter before the SNUR is published.

D. Timing of Section 5 Regulation

Generally, when a PMN substance is targeted for regulation under a section 5(e) Order, the statutory 90-day review period must be suspended to allow sufficient time for Order development, review, and approval. In such cases, the PMN submitter may not commence production of the substance until the Order has been executed and all suspensions of the review period have expired. This process normally takes 3 to 6 months. In contrast, a PMN substance targeted for regulation under a non-5(e) SNUR does not generally require suspension of the review period beyond the initial 90 days because the specific use identified in the PMN does not present an unreasonable risk; rather, it is other potential uses of the PMN substance for which the Agency has concerns and for which the non-5(e) is developed. Consequently, PMN submitters of non-5(e) regulated substances may generally begin commercial production on the 91st day after submission of the PMN.

IV. Economic Analysis

The Agency's complete economic analysis is available in the public record for this rulemaking (OPPTS-50595). The regulatory impact analysis estimates the costs and benefits attributable to the

proposed regulation. In this case, the analysis also contains estimates for the three additional proposed amendments to section 5 regulations that are published elsewhere in this Federal Register. These proposals would amend the PMN rule, the Low Volume Exemption Rule, and the Polymer Exemption Rule. As these proposed regulations are amendments to current regulations, the costs and benefits are incremental, estimating the effect of the proposal with respect to the current regulation.

This non-5(e) SNUR amendment would eliminate the need to develop a section 5(e) Consent Order in those cases where EPA determines that activities described in the PMN submission will not present unreasonable risk. The major industry benefit is the avoidance of the delay and costs associated with negotiating a Consent Order; generally, the submitter will be able to commence commercial manufacture immediately after the PMN review period. The submitter, along with other manufacturers and processors, will be bound by the expedited SNUR.

Industry savings from this amendment due to the avoidance of Consent Orders have not been quantified. Annual government savings are estimated to range from \$240,000 to \$960,000, depending on the number of submissions (range used was 1,000 to 3,000 annually).

V. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS-50595). The record includes basic information considered by the Agency in developing this proposed rule. A public version of the record without any confidential information is available in the TSCA Public Docket Office from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE-G004, 401 M St., SW., Washington, DC.

VI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this proposed rule would not be a "major" rule because it would not have an effect on the economy of \$100 million or more, and it would not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA

estimates that the cost for submitting a significant new use notice would be approximately \$4,500 to \$11,000, including a \$2,500 user fee payable to EPA to offset EPA costs in processing the notice.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq., and have been assigned OMB control number 2070-0012.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: January 19, 1993.

William K. Reilly,
Administrator

Therefore, 40 CFR Chapter I, part 721 is proposed to be amended as follows:

PART 721 — [AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By revising § 721.170(c)(1) to read as follows:

§ 721.170 Modification requirements for selected new chemical substances that have completed premanufacture review.

* * * * *

(c) * * * (1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part, as well as activities not listed in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

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